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Award Number: W81XWH-04-1-0159

TITLE: Preventing Health Damaging Behaviors in Male and Female
Army Recruits

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT: Health damaging behaviors of young military personnel are reflections of health problems facing all young people in the U.S. Military life presents opportunities and challenges that may both protect and place young troops at risk for health damaging behaviors. Challenges for maintaining a healthy armed force include high rates of sexually transmitted infections (STIs), unintended pregnancies (UIPs), misuse of alcohol/substances, and personal sexual violence defined as violence within one's personal (dating or marital) relationships. The common thread through these negative health outcomes is volitional behavior. Such behaviors do not only result in illness or injury, but also negatively impact performance of military duties and threaten military readiness. Despite military leadership in setting standards and policies regarding professional behavior and universal health care for preventing and eliminating such negative health outcomes, many health problems remain. Building on our previous military research, we plan to develop and evaluate a cognitive-behavioral, skills-building intervention to prevent and reduce young troops' risk for STIs, UIPs, alcohol/substance misuse, and personal sexual violence. This research also seeks to establish the best training practices for educating young troops about health issues that impact military performance and readiness. Finally, it will have direct implications for health promotion and disease prevention education strategies designed to reach military men and women early in their careers.					
15. SUBJECT TERMS Health Promotion; Disease Prevention; Education and Intervention					
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3. INTRODUCTION

This study will utilize a group, randomized controlled study design to evaluate the effectiveness of a cognitive-behavioral intervention to: (1) prevent sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with personal sexual violence among Army recruits; (2) reduce participants' risk for STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with personal sexual violence by (a) decreasing gaps in knowledge and misperceptions about risk and prevention, (b) increasing motivation to change risk behaviors, (c) building effective skills to engage in health promoting behaviors, (d) decreasing sexual risk behavior; and (3) determine the best strategy for educating participants about the sensitive health matters such as STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with personal sexual violence. Additionally, all participants will complete self-administered questionnaires and will be screened for STIs (*C. trachomatis* and *N. gonorrhoeae*) at baseline and 9-12 months post-intervention and will be screened for pregnancy/UIP 9-12 months post intervention.

4. BODY

Research activities accomplished to date are detailed below.

STATEMENT OF WORK (SOW)

1. Brief commanding officers of the Department of the Army, Headquarters, U.S. Army Training Center and Fort Jackson, Fort Jackson, SC.
 - a. We have briefed COL Thomas Hayden, COL James Mundy, COL Dunemn, LTC Larry Andreo, and LTC Sonya Corum.

This activity was completed in May 2006.

2. Conduct focus groups to assist in the development of: (1) comparable gender-specific interventions to reduce health damaging behaviors associated with sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and personal sexual violence; and (2) pre- and post-intervention self-administered questionnaires to assess knowledge, attitudes, and beliefs, and behaviors associated with STIs, UIPs, alcohol and other substance misuse, and personal sexual violence.

This activity was completed in September 2007. See a detailed summary below.

- a. Institutional Review Board (IRB) approval to conduct focus groups was received from the United States Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office in May 2007 and the University of California, San Francisco, Committee on Human Research, initially in March 2007 and re-approved with modifications requested by the USAMRMC Human Subjects Research Review Board (HSRRB) May 2007.

- b. The primary purpose of the focus groups (anonymous small-group discussions) was to determine the best intervention strategy to affect behavioral change among soldiers in Advance Individual Training (AIT) at Fort Jackson, the group who will be the focus of this intervention research to prevent sexually transmitted infections (STIs) and unintended pregnancies (UIPs). Another purpose of the focus group discussions was to better understand AIT soldiers' knowledge, attitudes, beliefs, and behaviors related to risk and prevention of STIs, UIPs, and alcohol and substance misuse. In addition, the information gathered from the focus group discussions was to better understand the Army-specific context in which health behaviors occur. For example, we were interested in learning how a recent or impending deployment may influence risk for STIs, UIPs, and alcohol and substance misuse.
- c. Six separate male and female focus groups were conducted at Fort Jackson in Columbia, SC on September 28-29, 2007. Four groups were among soldiers in AIT (two male and two female groups) and two groups among junior enlisted personnel (one male and one female group).
- d. Results of the focus group discussion indicate a clear need for Army-specific interventions to prevent the risk of behaviors related to the acquisition and transmission of STIs and UIPs by increasing accurate knowledge, improving protective attitudes, enhancing motivation to enact behavior change, increasing communication, problem-solving, and decision-making skills to reduce STI- and UIP-related skills. Specifically, three major areas of potential risk were identified:
 - a.) In male-female soldiers social interactions during periods of leave
 - b.) During weekend leaves male and female AIT soldiers socialize at clubs, malls, and other places. While all do not engage in activities that may increase their risk for STIs and UIPs, some do drink and engage in unprotected sexual behavior.
 - c.) Although some indicated knowledge regarding methods of reducing risk, including abstinence from drinking or drinking in moderation and/or abstinence from sexual activity or using barrier methods to reduce risk during sexual behavior, some reported limited or incorrect knowledge, negative attitudes, a lack of motivation and skills to reduce their risk while engaging in these behaviors.
 - d.) Both male and female soldiers indicated that STIs and UIPs are of concern for them and heard of instances where these negative health outcomes have occurred.
 - e.) Some soldiers reported that going to the Troop Medical Clinic is a great place to go for reproductive health concerns such as STIs or pregnancy, some indicated concern that their health information would not be kept privacy, which may prevent them from seeking healthcare in a timely manner or for prevention purposes.
 - f.) When transitioning from AIT training to their first duty station, junior enlisted soldiers, especially female soldiers, reported knowledge of instances when soldiers first arrive to a new duty station, they receive a great deal of attention from male soldiers. It was reported that some soldiers are motivated by genuinely helping the "newbie" and some are motivated by possible opportunities for selfish reasons such as garnering attention or even dates. Some soldiers perceived this to be a

- particularly vulnerable time for female soldiers, especially those who are naïve or unsuspecting of the other the person(s) motives.
- g.) Some soldiers (especially female soldiers) indicated that there is a need for training to give young male and female soldiers skills about how to handle social transitions to a new post.
- e. When learning about their initial deployment abroad (e.g., Iraq)
- a.) Both male and female soldiers reported feelings of being prepared for deployment in terms of their technical skills, but reported apprehension about the unknown and unexpected things to come; concern that family members and other love ones will worry about them; and unease about not having opportunities for rest and relaxation during long periods of deployment.
 - b.) As a result of these concerns, some soldiers reported an accelerated rate of engaging in some behaviors including drinking more and/or engaging in sexual activity.
 - c.) Along these lines some reported (males) wanting to make sure they leave a legacy (child) behind if the event that they do not return from deployment, thus prompting opportunities for engaging in unprotected sexual intercourse.
3. Develop comparable gender-specific interventions for male and female Army recruits to: (1) prevent acquisition of STIs and UIPs; and (2) reduce the risk of STI- and UIP-related behaviors including alcohol and other substance misuse, and personal sexual violence. This activity was completed in December 2008. See a brief summary below.
- a. Army-specific interventions were developed on the basis of results of the focus groups and on the basis of current literature in the fields of STI/HIV prevention, nutrition, fitness, and physical injury prevention. Specifically, we developed curriculum, including the training manual for the STI/UIP prevention intervention, and an Army-specific video to reinforce health promotion information. The video is entitled, *Off Post*. The intervention is entitled, *Staying Safe and in Control: Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancies*. See our previous annual report dated 21 January 2009 for a detailed outline of the modules for each of the five sessions of the intervention's training manual. In addition, for the comparison group, an intervention was developed that focused on nutrition, physical fitness, and injury prevention was developed. This intervention is entitled, *Fit You: Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention*. See our previous annual report dated 21 January 2009 for a detailed outline of the intervention's training manual. Finally, based on our focus group discussions, as noted above, it is apparent that due to the manner in which AIT soldiers are trained and the common concerns, the focus of the interventions will be co-ed, but they could be readily administered separately for male and female soldiers. A brief overview of both intervention curricula are outlined below.

The research is being carried out at Fort Jackson, under the guidance and support of the U.S. Army Basic Combat Training Center of Excellence (USABCTCoE). Within the USABCTCoE, LTC Sonya J. Cable remains our first-line contact person who is working

closely with us to logistically implement the study's activities. Our current research activities are being carried out within Fort Jackson's Advance Individual Training Command in the 187th Ordnance Battalion under the leadership of Battalion Commander LTC Darrell Aubrey. Our direct point of contact is CPT Burton Milnor, Jr., the S3 officer for the 187th Ordnance Battalion.

In order to accomplish the remaining SOW activities, we received Institutional Review Board (IRB) approval from the University of California, San Francisco, Committee On Human Research (CHR) (see approval letter and Appendix 1) and the USAMRMC Human Subjects Research Review Board (HSRRB) (see approval letter in Appendix 2).

4. Pilot-test the gender-specific interventions, self-administered questionnaires, and the biological specimen collection protocol for feasibility.

This activity was completed in October 2010. It is important to note that since we are working within the 187th Ordnance Battalion the number the ratio of men to women is on average two or three to ten, thus it is not logistically feasible to conduct separate gender-specific interventions.

5. Implement the intervention within the context of basic training.

This activity is currently underway. To date, we have enrolled 67 AIT soldiers (56 male and 11 female soldiers) in the randomized controlled intervention. Soldiers are randomized by series (company) into the *Staying Safe and in Control: Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancies* experimental intervention (n = 28) or the *Fit You: Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention* control intervention (n = 39).

Also, it is important to note that at the request of the 187th Battalion, we reduced the number of intervention session from five to four so that participation in the study would not interfere with the soldiers' AIT training. The same topics remain, but the length of the modules was reduced to accommodate this request.

The remaining SOW activities have yet to be completed as they are contingent upon complementation of the study's implementation.

6. Conduct a 12-month follow-up of intervention participants.
7. Evaluate the effectiveness of each gender-specific intervention and compare differences across interventions on study participants' acquisition of STIs and UIPs during their first year of military service.
8. Examine key sub-questions related to STIs and UIPs: (1) assess psychosocial, behavioral, and contextual factors associated with STIs and STI-related risk at baseline and STIs and UIPs at follow-up; (2) document the prevalence of personal sexual violence at basic training entry; (3) examine relationships among personal sexual violence, STIs, and STI-related risk

at baseline and STIs and UIPS at follow-up; and (3) determine the relationship between alcohol and other substance misuse and personal sexual violence and the relationship of these factors to STIs and STI-related risk at baseline and STIs and UIPS at follow-up.

9. Disseminate study findings through: (1) briefs given to participating military commands; (2) presentations at military-specific preventive medicine meetings as well as annual scientific meetings; and (3) publications submitted to scientific journals.

5. KEY RESEARCH ACCOMPLISHMENTS TO DATE

Our research accomplishments to date include: (1) Identification of a suitable cohort in which to implement the proposed research (see description of these activities in the Body section above. (2) Examination of scientific literature and published interventions in order to identify elements of effective interventions to prevent STIs, UIPs, alcohol and other substance misuse, and personal sexual violence to guide the development of interventions in the proposed research. (3) Completion of focus group discussions served as the foundational material for the development of the intervention to prevent STIs and UIPs in soldiers undergoing AIT trainees. (4) Completion of the curriculum, including the training manuals for both the experimental and control group arms of the study, as well as the pre-test questionnaire and a protocol for implementation. (5) Pilot-test the experimental and control interventions, baseline self-administered questionnaire, and the biological specimen collection protocol for feasibility. As noted above, this activity was accomplished in October 2010. (6) Intervention activities are currently underway. Thus far, we have demonstrated that we can successfully enroll, retain, and engage AIT soldiers in study activities.

6. REPORTABLE OUTCOMES

There are no reportable outcomes to date.

PROPOSED PROJECT ACTIVITIES:

Our plans for the coming year include completing SOW activities outlined in item 5 above. Specifically, we plan to complete the implementation of the randomized controlled intervention trial within the context AIT, Fort Jackson, SC. In addition, we will begin planning for the post-intervention follow-up.

7. CONCLUSIONS

There are no scientific conclusions that can be made at this time.

8. REFERENCES

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9. APPENDICES

Appendix 1: University of California, San Francisco, Committee on Human Research (CHR)
CHR Approval Letter

Appendix 2: USAMRMC Human Subjects Research Review Board (HSRRB) Approval Letter

10. SUPPORTING DATA

None.

Appendix 1.

**UCSF CHR Approval Letter,
December 2010**



**Human Research Protection Program
Committee on Human Research**

Notification of Full Committee Approval

Principal Investigator

Cherrie B Boyer

Co-Principal Investigator

Mary-Ann B Shafer

Type of Submission: Continuing Review Submission Form

Study Title: Preventing Health Damaging Behaviors in Male and Female Army Soldiers

IRB #: 10-04317

Reference #: 011824

Reviewing Committee: Parnassus Panel

Study Risk Assignment: Greater than minimal

Approval Date: 11/18/2010

Expiration Date: 12/10/2011

Regulatory Determinations Pertaining to This Approval (if applicable): Individual HIPAA authorization is required.

IRB Comments (if applicable):

Expiration Notice: The iMedRIS system will generate an email notification eight weeks prior to the expiration of this project's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the completion of the project.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval. The CHR [website](#) has more information.

Appendix 2.

**HRPO Approval Memorandum
Award Number
W81XWH-04-1-0159**

From: Brosch, Laura R Dr CIV USA MEDCOM USAMRMC [Laura.Brosch@us.army.mil]
Sent: Wednesday, March 17, 2010 12:35 PM
To: Boyer, Cherrie
Cc: Bennett, Jodi H Ms CIV USA MEDCOM USAMRMC; Burdette, Buffy J Ms CTR US USA MEDCOM USAMRMC; Herndon, Dana L Ms CIV USA MEDCOM USAMRAA; Brosch, Laura R Dr CIV USA MEDCOM USAMRMC; Duchesneau, Caryn L Ms CIV USA MEDCOM USAMRMC; Wilberding, Julie A Dr CTR US USA MEDCOM USAMRMC; Eaton, Karen M Ms CTR US USA MEDCOM USAMRMC; Bonilla-Vazquez, Pedro MAJ MIL USA
Subject: A-12373.2 HRPO Approval Memorandum (Proposal Log Number 03210001, Award Number W81XWH-04-1-0159) (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: NONE

SUBJECT: Initial Approval for the Protocol, "Preventing Health Damaging Behaviors in Male and Female Army Soldiers," Submitted by Cherrie B. Boyer, PhD, University of California, San Francisco, San Francisco, California, in Support of the Proposal, "Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During the First Tour of Duty," Proposal Log Number 03210001, Award Number W81XWH-04-1-0159, HRPO Log Number A-12373.2

1. The subject protocol (dated 11/17/09) was approved by the University of California, San Francisco Committee on Human Research (UCSF CHR) on 11 January 2010. This protocol was reviewed by the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, U.S. Army, and USAMRMC human subjects protection requirements.
2. This no greater than minimal risk study is approved for the enrollment of 3,850 subjects.
3. The following are reporting requirements and responsibilities of the Principal Investigator to the HRPO. Failure to comply could result in suspension of funding.
 - a. Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. Major modifications include a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in age range or change in/addition to the study population, or a change that could potentially increase risks to subjects.
 - b. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email (hsrrb@amedd.army.mil), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RP, 504 Scott Street, Fort Detrick, Maryland 21702-5012.
 - c. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the Institutional Review Board, the institution, the Sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.

- d. Any deviation to the protocol that may have an adverse effect on the safety or rights of the subject or the integrity of the study must be reported to the HRPO as soon as the deviation is identified.
 - e. A copy of the continuing review approval notification by the UCSF CHR must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the UCSF CHR is due no later than 10 December 2010. Please note that the HRPO also conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.
 - f. The final study report submitted to the UCSF CHR, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.
 - g. The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research; the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions; and any instances of serious or continuing noncompliance with the regulations or requirements must be reported immediately to the HRPO.
4. Please Note: The USAMRMC ORP HRPO conducts random site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.
5. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer or Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.
6. The HRPO point of contact for this study is Karen M. Eaton, MS, Human Subjects Protection Scientist, at [301-619-9268/karen.m.eaton@us.army.mil](mailto:karen.m.eaton@us.army.mil).

LAURA RUSE BROSCH, RN, PhD

Director, Office of Research Protections

Human Research Protection Office

U.S. Army Medical Research and Materiel Command

Note: The official copy of this approval memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 504 Scott Street, Fort Detrick, MD 21702. Signed copies will be provided upon request.

Classification: UNCLASSIFIED

Caveats: NONE